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09/232,880 01/15/99 XU

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EXAMINER

HARRIS, A

| ART UNIT | PAPER NUMBER |
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1642

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DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/232,880

Applicant(s)

Xu et al.

Examiner
Alana M. Harris, Ph. D.

Group Art Unit
1642



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-25 is/are pending in the application.
- Of the above, claim(s) 1-6 and 13-25 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 7-12 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, filed March 12, 1999.
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

DETAILED ACTION

1. Applicant's election without traverse of Group II (claims 7-12), SEQ ID Nos:45, 67, 107, 308, 311, 313 and 326 in Paper No.7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-25 are pending.

Claims 1-6 and 13-25, drawn to non-elected inventions are withdrawn from examination.

Claims 7-12 are examined on the merits.

Priority

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. § 120. The Examiner has reviewed U.S. Applications Serial NOs: 09/159,882, filed September 23, 1998 which is a continuation-in-part of 09/116,134, filed July 14, 1998 and 09/020,747, filed February 9, 1998 from which priority is claimed. The limitations of all the sequences, SEQ ID Nos:45, 67, 107, 308, 311, 313 and 326 are not disclosed in the aforementioned applications. U.S. Applications Serial No. 09/030,606, filed February 25, 1998 and 08/904,809, filed August 1, 1997, which is a continuation-in-part of U.S. Application Serial No.08/806,596, filed February 25, 1997 were not available for the Examiner's review. Thus, claims 7 and 10 and its dependent

Art Unit: 1642

claims, 8, 9, 11 and 12 will be granted the priority date of January 15, 1999, the effective filing date of the instant Application No. 09/232,880.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7 and 10 are broadly drawn to methods for determining the presence or absence of prostate cancer and monitoring the progression of a cancer in a patient, which includes contacting a biological sample with polynucleotide sequences that encode portions of various of a prostate tumor proteins. The claims utilize the following sequences: SEQ ID NOs:45, 67, 107, 308, 311, 313 and 326. Thus, the cited claims are broadly drawn to a genus of nucleic acid molecules that encompass a larger nucleic acid. Although the specification states on pages 11 and 12 that it is possible to obtain a full length cDNA sequence and utilizing the recited expressed sequence tags to generate a contiguous full length sequence, the specification does not describe any of the

Art Unit: 1642

structural elements of a gene that would encode these actual DNA sequences of promoter and regulatory regions and introns, all defining elements of a "gene". The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Likewise, the specification does not contain any disclosure of the function of a full length open reading frame (ORF) that includes SEQ ID NOs:45, 67, 107, 308, 311, 313 and 326, specified unique fragments. The genus of cDNAs including SEQ ID NOs:45, 67, 107, 308, 311, 313 and 326 is very large and members of the genus are variable because of the potentiality of the many different proteins they may encode. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1642

7. Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitations "oligonucleotide that hybridizes to a polynucleotide " and "...polynucleotide that hybridizes to the oligonucleotide..." in claims 7-12 are not clear. The metes and bounds are unclear and in the absence of limitations specifying specific stringency conditions.

b. Claims 7 and 10 are vague and indefinite in the recitation of non-elected SEQ ID NO. Applicant is advised to delete those sequences not examined in the instant application.

Claim Rejections - 35 U.S.C. § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 7-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible or a well established utility.

The applicant has asserted several utilities for the claimed nucleic acid molecules to be used in the claimed methods. The specification asserts the following utilities for the claimed

Art Unit: 1642

nucleic acid molecules, consisting of SEQ ID Nos:45, 67, 107, 308, 311, 313 and 326, as well as variants of the fragments: probes, amplification primers for determining expression, medicaments and in the identification of homologous clones. However, these asserted utilities are not credible, specific or substantial. The broadly claimed nucleic acids are based on the aforementioned sequence identification numbers that encode portions of tumor prostate proteins. Other than the nucleotide sequence identification numbers, the reference of their subsequent polypeptide products and given lab designation acronyms, the specification provides no functional characterization of the subsequent polypeptides. How can one skilled in the art be sure that these fragments of sequences could be conclusively used in the diagnosis of prostate cancer? The specification seems to suggest that some of the novel fragments are not only present or expressed in normal and tumor prostate, but in the liver, pancreas and ovary. Consequently there is no information that links expression of the resulting polypeptides to any specific tissue. Thus, the asserted utility of the claimed nucleic acids is not substantial, specific or credible.

Claims 7-12 are also rejected under 35 U.S.C., first paragraph. Specifically, since the claimed invention is not supported by either and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Art Unit: 1642

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 7-12 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/37418 (August 27, 1998). Document WO 98/37418 (see pages 2-3, 13 and 18 and accompanying nucleic acid database sheet, Accession # V58522) disclose methods for determining the presence or absence of prostate cancer in a patient and for monitoring the progression of a cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an oligonucleotide that hybridizes to a polynucleotide that encodes a prostate tumor protein, wherein the prostate tumor protein comprises an amino acid sequence that is encoded by a polynucleotide sequence selected from the group consisting of:

- (i) polynucleotides recited in any one of SEQ ID Nos: #45, 67 and 107 and
- (ii) complements of the foregoing polynucleotides; and

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide, relative to a predetermined cut-off value, and therefrom determining the presence or absence of a cancer in the patient (claims 7 and 10) ;

Art Unit: 1642

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time;

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient.

In addition, both methods determine the amount of polynucleotide that hybridizes to the oligonucleotide using polymerase chain reaction and a hybridization assay (claims 8, 9, 11 and 12).

12. Claims 7-12 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/37093 (August 27, 1998). Document WO 98/37093 (see pages 13, 16-17 and 21 and accompanying nucleic acid database sheet, Accession # V61287) disclose methods for determining the presence or absence of prostate cancer in a patient and for monitoring the progression of a cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an oligonucleotide that hybridizes to a polynucleotide that encodes a prostate tumor protein, wherein the prostate tumor protein comprises an amino acid sequence that is encoded by a polynucleotide sequence selected from the group consisting of:

- (i) polynucleotides recited in any one of SEQ ID Nos:#45, 67 and 107 and
- (ii) complements of the foregoing polynucleotides; and

Art Unit: 1642

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide, relative to a predetermined cut-off value, and therefrom determining the presence or absence of a cancer in the patient (claims 7 and 10) ;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time;

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient.

In addition, both methods determine the amount of polynucleotide that hybridizes to the oligonucleotide using polymerase chain reaction and a hybridization assay (claims 8, 9, 11 and 12).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
July 19, 2000



NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER